

**Notice of Allowability**

Application No.

10/056,052

Applicant(s)

PATTI ET AL.

Examiner

Art Unit

Zachariah Lucas

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE and amendment of November 2, 2004.
2. ☒ The allowed claim(s) is/are 46-55,57 and 59-74.
3. ☒ The drawings filed on 19 April 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 12-10-2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 1-26-2005.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Currently, claims 46-78 are pending in the application. In the prior action, mailed on May 19, 2004, claims 1-7, 9-12, 16-26, 32, and 37-45 were pending in the application. Of those claims, claims 1-7, 9, 10, 15-17, 19, 23, 24, 26, 32, and 37 were under consideration; claims 11 and 12 were objected to; and claims 18, 20-22, 25, and 38-45 were withdrawn as to non-elected inventions. Along with the Request for Continued Examination (RCE) filed on November 2, 2004, the Applicant submitted an amended claim set in which all previously pending claims were cancelled, and new claims 46-78 were added.
2. In the Examiner's Amendment below, claims 46, 48, 55, 57, and 63-65 have been amended; and claims 56, 58, and 75-78 have been cancelled.
3. The restriction requirement between antibodies 12-9 and 13-2 is withdrawn, and is the restriction between these antibodies, and the methods of using or making them of pending claims 62, 64, and 65.
4. Claims 46-55, 57, and 59-74 are allowed as amended below.

## **EXAMINER'S AMENDMENT**

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Art Unit: 1648

Authorization for this examiner's amendment was given in a telephone interview with B. Aaron Schulman on January 26, 2005.

The application has been amended as follows:

Claims 56, 58, and 75-78 have been cancelled.

Claim 46 has been amended to read as follows:

46. A monoclonal antibody which binds to an epitope that is recognized by a monoclonal antibody selected from the group consisting of monoclonal antibodies 12-9 and 13-2.

Claim 48 has been amended by deleting the phrase "or prevents" in line 1 of the claim.

Claims 55 and 57 have been amended to read as follows:

55. The antibody according to claim 46 having a variable light chain having the amino acid sequence SEQ ID NO: 18 and a variable heavy chain having the amino acid sequence SEQ ID NO: 20.

57. The antibody according to claim 46 having a variable light chain sequence encoded by a nucleic acid having the sequence SEQ ID NO: 17, or degenerates thereof, and a variable heavy chain sequence encoded by a nucleic acid having the sequence of SEQ ID NO: 19, or degenerates thereof.

Claim 63 has been amended by deleting the phrase "or preventing" in line 1 of the claim.

Art Unit: 1648

Claim 64 has been amended by deleting the phrase "or preventing" in line 1 of the claim.

Claim 65 has been amended by inserting the phrase - - and screening said hybridoma for reactivity with said epitopes- - at the end of the claim.

As indicated in the Interview Summary of January 26, 2005, the claims have been amended to remove reference to the non-elected antibodies 35-220 and 35-006 (and to sequences associated thereto).

Claims 48, 63, and 64 have been amended to remove reference in the claims to the prevention of *S. aureus* infection. While the Applicant appears to have enabled the use of the antibodies to treat such infections (see, application pages 32-33, and the Hall reference), the application has not demonstrated that these antibodies are able to prevent such infections.

Claims 55 and 57 have been amended to associate the specific variable light chain of the humanized 12-9 antibody with the appropriate variable heavy chain. This amendment was made for the reasons indicated with respect to claims 11-14, 26-31, and 33-36 in the Non-Final rejection of August 27, 2003. I.e., while the Applicant is enabled for the use of an antibody comprising both the variable light and heavy chains, the applicant has not met the enablement or written description requirements for any antibody comprising either the variable light chain, or the variable heavy chain.

Claim 65 has been amended to clarify that the claimed antibodies bind the specific epitopes bound by the 13-2 or 12-9 antibodies.

***Information Disclosure Statement***

6. The information disclosure statement (IDS) submitted on December 10, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

***Claim Rejections - 35 USC § 103***

7. **(Prior Rejections- Withdrawn)** Claims 1-10, 15, 19, 23, 24, and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al., U.S. Patent 6,008,341. Claims 16 and 17 were as being unpatentable over Foster in view of Na (Clin Diagn Lab Immunol 6: 924-29). Claim 26 was rejected as being unpatentable over Foster in view Sieradzki et al. (J Antimicrob Chemother 39: 47-51). Claim 32 was rejected as being unpatentable over Foster in view of Hook (U.S. Patent 6,288,214) and Emery (U.S. 6,027,736). In the Response to the prior action, and in the Examiner's Amendment above, all previously pending claims were cancelled and the new claims amended to read on antibodies directed to the specific epitopes recognized by antibodies 12-9 and 13-2. These antibodies have been shown, either on pages 32-33 of the application in the Hall et al. reference (Infect Immun 71: 6864-70) cited by the Applicant in the Patti Declaration of March 2, 2004, to be effective for the treatment of infection by *S. aureus*. The prior art does not provide enabling disclosure for the use of antibodies against ClfA, with the claimed specificity, effective for the treatment of *S. aureus* infection. . As these specific antibodies, and the epitopes recognized thereby, do not appear to have been disclosed by the art, the rejection of the previously pending claims are not extended to the new claims.

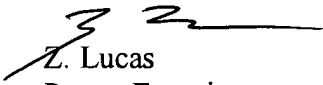
Art Unit: 1648


***Conclusion***

8. Claims 46-55, 57, and 59-74 are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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